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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,575	03/31/2004	Ilya Malyarov	00390061AA	4329

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RESTON, VA 20190

EXAMINER

BEX, PATRICIA K

ART UNIT	PAPER NUMBER
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1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/813,575

Applicant(s)

MALYAROV ET AL.

Examiner

P. Kathryn Bex

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 1-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." See for example, patent no. 5,637,275 at page 2, line 10. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Incorporation By Reference

2. The attempt to incorporate subject matter into this application by reference at page 6, line 17; page 7, line 12; and page 9, line 12 of the specification is ineffective because it fails to identify the document by an application or patent number. The reference document is not clearly identified as required by 37 CFR 1.57(b)(2)). Moreover, the root words "incorporate" and "reference" have been omitted, See 37 CFR 1.57(b)(1).

3. The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective.

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Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter see 37 CFR 1.57(f).

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "transfer device" in claim 1; the "mechanism for moving" the housing in claims 5,7,8,9; the "means for biasing" in claim 6; the "continuous carousel or chain" in claims 10 and 11; and "plurality of vessel receptacles" in claim 10, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

5. The drawings are objected to under 37 CFR 1.83(a) because they fail to show "detection mechanism 4" in Fig. 3 as described in the specification at sentence bridging pages 8 and 9, last line. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

6. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicants will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the "transfer device" in claim 1 and "plurality of vessel receptacles" in claim 10 are not disclosed in the specification.

Claim Objections

8. Claims 1-17 are objected to because of the following informalities: claim 1, last line ends with “, and”. This should be replaced with a period.

9. Claims 9 and 11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In this instance, claim 9 is identical to claim 7, from which it depends. Claim 11 is objected to due to its dependence from 9.

10. Claim 13 is objected to because the claim ends with a comma instead of period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They are replete with grammatical and idiomatic errors.

For example, claim 1, recites a “transfer device” for transferring one of the plurality of vessels from the transport device into the housing. Examiner can find no

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mention of such a transfer device in the specification. Thus, this introduces confusion and uncertainty into the claims. Page 7, line 17, of the specification does broadly describe the test vessel is transferred to the read station; however, no device is taught.

Similarly, in claims 6, 7-9 Applicants recite "a mechanism for moving" the one of the plurality of vessels from an unshielded position to an unshielded position. The specification contains no mention of such a mechanism for moving. However, the specification does broadly teach the vessel is rotated [in the housing] around to a read position 10, see page 8, lines 29-31. For examination purposes, the mechanism for moving has been interpreted to mean the motor for moving the housing. In addition, the specification does not disclose a "plurality of vessel receptacles" for receiving each of the plurality of vessels, as recited in claim 10.

Claims 14 and 16 recite the limitation "said any one of at least two attenuation positions" in line 2, respectively. There is insufficient antecedent basis for this limitation in the claim. For the purposes of examination, claims 14 and 16 have been treated as depending from claim 13.

In addition, claim 16, recites "wherein any one of at least three attenuation positions". Claim 16 depends from claim 12. There is no "at least three attenuation positions" in claim 12. However, there are disclosed only at least two in claims 13 and 14. For the purposes of examination, the Examiner has interpreted this limitation in claim 16 to mean "at least two attenuation positions" as disclosed in claims 13 and 14.

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Moreover, it is not clear from claim 13, what the difference is between the "attenuation means" and the "attenuation device". This appears to be unnecessarily tautological.

It is respectfully requested that Applicants clarify of all of the aforementioned defects.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ammann et al. (US Patent no. 6,335,166).

Ammann *et al* teach an analyte detection station for an automated immunoassay analyzer, comprising:

a housing (950, 1372, Figs. 40-51; col. 51, line 50- col. 60, line 4);

a detector (photomultiplier tube 959) for detecting radiant energy. The detector is connected to the housing (see Fig. 43);

a transport device 1332 for transporting a plurality of vessels 160, each of the vessels containing at least one bound analyte and at least one compound for emitting radiant energy or color; and

a transfer device for transferring one of the plurality of vessels

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from the transport device into the housing (via side door assembly 1200).

The housing having a shield (i.e., shutter 1232) for shielding radiant energy emanating from a source outside of the housing from being detected by the detector. Thus, only radiant energy from the one of the plurality of vessels is detected by the detector.

Regarding claims 2 thru 4, please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., chemiluminescence, fluorescence, phosphorescence, etc.,) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches *all the structural limitations* of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). While Ammann *et al* do not explicit teach a detector that detects phosphorescence, such a limitation is merely an intended use, which the prior art would inherently be capable of doing. The only distinction between applicants' claims and the prior art is recited functional language. It is incumbent upon Applicants to show that the application disclosed by the prior art is not actually capable of performing such functions. See *In re Ludtke*, 169 USOQ 563 (CCPA 1971). Moreover, Ammann *et al* teach fluorescent, chemiluminescent detection (see claim 26).

With respect to claims 5 and 7, the inlet housing includes a mechanism for rotatably moving one of the plurality of vessels 1120 from an unshielded position when it is transferred from the transport device to the housing to a shielded position when the detector is detecting radiant energy.

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Regarding claim 6, Ammann *et al* teach a means for biasing 1304 the vessels (Fig. 47) in the station a set distance from the detection mechanism (beginning at col. 57, line 10.)

With respect to claim 8, the side door housing 1200 moves the vessels to a disposal station (col. 59, lines 5-21.)

Regarding claims 10 and 11, the transport device of Ammann *et al* is a continuous belt that includes a holder 1302 designed to receive the plurality of vessels 160. The belt can receive the vessel at a plurality of locations 1200 (located on either side of the apparatus; Fig. 43).

With respect to claims 12-17, Ammann *et al* teach an attenuation means (rotatable shutter 1270) for attenuating light signals. The attenuation means and is located between the housing and the detector, wherein the attenuation device can be set at any two attenuation positions. These positions include: an unattenuated position where light from the vessel can be read directly by the detector through aperture 1280, and a dark position where no light from the vessel can be read by the detector.

15. Claims 1-5 and 7-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Babson *et al*. (US Patent no. 5,885,529).

Babson *et al* teach an analyte detection station for an automated immunoassay analyzer, comprising:

a housing 216 (reaction reading station; col. 8, line 31; Figs. 2a, 2b);

a detector (photomultiplier tube 216a) for detecting radiant energy. The detector is connected to the housing since it is described as part of the detector station (see col. 9 lines 21-22; Figs. 2a and 2b);

a transport device 213a for transporting a plurality of vessels 27, each of the vessels containing at least one bound analyte and at least one compound for emitting radiant energy or color; and

a transfer device 214, 215a for transferring one of the plurality of vessels from the transport device into the housing (photomultiplier tube station).

The housing of Babson *et al* has a shield (i.e., shutter; not shown but disclosed at col. 9, lines 27-30) for shielding radiant energy emanating from a source outside of the housing. Thus, only radiant energy from one of the plurality of vessels is detected by the detector.

Regarding claims 2 thru 4, please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., chemiluminescence, fluorescence, phosphorescence, etc.,) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches *all the structural limitations* of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). While Babson *et al* do not explicit teach a detector that detects phosphorescence, such a limitation is merely an intended use, which the prior art would inherently be capable of doing. The only distinction between applicants' claims and the prior art is recited functional language. It is incumbent upon Applicants to show that the application disclosed by the prior art is not actually capable of performing such

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functions. See *In re* Ludtke, 169 USQ 563 (CCPA 1971). Moreover, Babson *et al* explicitly teach fluorescent, radioactive, chemiluminescent detection (col. 1, lines 20-34 and col. 8, lines 40-64).

With respect to claims 5 and 7, the housing of Babson *et al* includes a mechanism for rotatably moving one of the plurality of vessels (i.e., motor which drives the transport device 213a) from an unshielded position when it is transferred from the transport device to the housing to a shielded position when the detector is detecting the radiant energy.

With respect to claim 8, the motor of the transport device moves the vessels to a disposal station (col. 8, lines 32-33.)

Regarding claims 10 and 11, the transport device is a continuous belt having teeth (i.e., receptacle vessels) that receive the plurality of vessels. The belt can receive the vessel at a plurality of locations.

With respect to claims 12-16, Babson *et al* teach an attenuation means (rotatable filter wheel) for attenuating light signals. The attenuation means is located between the housing and the detector, and can be set at any three attenuation positions (see col. 9, lines 21-49). The three attenuation positions include: an unattenuated position where light from the vessel can be read directly by the detector; an attenuated position where light from the vessel can be read by the detector through neutral density filter; and a dark position where no light from the vessel can be read by the detector.

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Regarding claim 17, the detection station of Babson *et al* include a means for measuring dark counts (i.e., computer 12). The computer uses these values to calibrate "noise" in the PMT (col. 9, lines 44-49.)

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicants are advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the

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examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ammann *et al* (US Patent no. 6,335,166) in view of Babson *et al* (US Patent no. 5,316,726).

The teachings Ammann *et al* have been summarized previously, *supra*. Ammann *et al* do not disclose a means for measuring dark counts for determining ambient light levels in the detection means. However, the use of a means for measuring dark counts is considered conventional in the analyzer art, see for example, Babson *et al*.

Babson *et al* disclose an analyzer that employs, *inter alia*, a filter wheel 302 in-between a photomultiplier 96 and assay tube 27. The detector is linked a computer 12, which measures the dark counts and thereby enables the analyzer to periodically calibrate for increased measurement accuracy (col. 8, line 43- col. 9, line 2).

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included in Ammann *et al* the filter wheel of Babson *et al* to enable the analyzer to periodically calibrate the detector for increased measurement accuracy.

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Conclusion

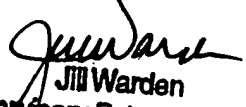
20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PKB
Examiner
Art Unit 1743


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